REMARKS

Claims 1, 12 and 22 have been amended. Support may be found in claim 2, as originally filed. Claim 2 has been canceled. No new matter has been added. Entry is requested..

Claims 1, 3-7 and 9-22 are pending.

Claims 1-7 and 9 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 3,491,070.

The examiner (office action, numbered paragraph 2, top of page 3) interprets applicants' claims as requiring polymer prepared from monomers selected from the group consisting of alkyl acrylate monomer, alkyl methacrylate monomer and polymerizable non-cyclic nitrogen-containing monomer, and as further requiring 50-98% alkyl acrylate monomers and/or alkyl methacrylate monomers. The examiner acknowledges that the claims also require a therapeutic agent.

US '040 is cited by the examiner as disclosing an adhesive obtained by the combination of monomers to form polymers consisting of 80-96% of 2-ethylhexyl acrylate and 2.0-19% octyl acrylamide to create a polymer combination that is synergistic in nature. The examiner refers to col. 1, lines 52-60. The examiner further urges that the Tg of applicants' claim 4 is inherent for the specific polymer. It is also the examiner's position that the pressure sensitive adhesive of US '040 further comprises ammonium persulfate that is a known antimicrobial agent, which reads on a therapeutic agent. The examiner refers to US 5,827,505 as evidence that ammonium persulfate is a known antimicrobial agent.

Applicants' claim 1 is directed to an adhesive composition comprising an acrylic polymer and a therapeutic agent. The acrylic polymer is made from monomers selected from the group

consisting of alkyl acrylate monomer, alkyl methacrylate monomer and polymerizable non-cyclic nitrogen-containing monomers. The alkyl acrylate monomer and alkyl methacrylate monomers used to prepare the polymer are further characterized as having up to about 18 carbon atoms in the alkyl group. The polymerizable non-cyclic nitrogen-containing monomers are further characterized as being selected from the group consisting of N-substituted acrylamide monomers, N-substituted methacrylamide monomers, vinylacetamides, nitriles, and mixtures thereof. The acrylic polymer required for use comprises, on a dry weight basis of the total monomer weight of the polymer, from about 50 to about 98% of the alkyl acrylate monomers and/or alkyl methacrylate monomers and from about 2 to about 50% of the polymerizable non-cyclic nitrogen-containing monomers, lacks functional groups containing reactive hydrogen moieties and contains no post-polymerization chemical crosslinker.

Applicants disagree that the claimed invention is anticipated by US '040.

The cited US '040 patent discloses adhesive compositions that comprise a polymer composition based on a specific acrylate monomer (2-ethylhexyl acrylate) and two specific acrylamide monomers (N-octyl acrylamide and methylacrylamide). As disclosed at col.1, lines 52-60, the US '040 invention is based on the discovery that a specific combination of two particular acrylamides with 2-ethylhexyl acrylate creates a combination that is synergistic in nature, and that all three monomers must be present in the adhesive composition.

The examiner has mischaracterized the teaching of US '040 by omitting the required and essential methylacrylamide monomer component of US '040. The polymer of US '040 must contain only 2-ethylhexyl acrylate, N-octyl acrylamide and methylacrylamide, and requires all three. Applicants' polymer is prepared from alkyl acrylate monomer and alkyl methacrylate monomers having up to about 18 carbon atoms in the alkyl group, N-substituted acrylamide

monomers, N-substituted methacrylamide monomers, vinylacetamides, and nitriles, and must contain 50 to about 98% of the alkyl acrylate and/or alkyl methacrylate monomers and from about 2 to about 50% of the recited nitrogen-containing monomers. No other monomers are included. Applicants "comprising" language refers to the adhesive composition, not to the acrylic polymer, which is recited as being prepared form monomers "selected from the group consisting of" only those specifically recited monomers. A methacrylamide, which is not N-substituted, is not included as a possible monomer component of applicants' acrylic polymer.

While the examiner urges that US patent 5,827,505 teaches that ammonium persulfate is a known microbial agent, this patent describes ammonium persulfate as a bleaching agent. While applicants concede that a bleaching agent may be considered as a therapeutic agent, Applicants disagree with the examiner's position that US '040 teaches an adhesive containing a therapeutic agent. In Example 1 of the US '040 patent, an adhesive polymer is prepared by combining water, dispersant, emulsifier, catalyst and monomer mixture in the amounts set forth in Table 1. Ammonium persulfate is used as an oxidizing agent/catalyst in an amount of 0.18 parts and would be completely consumed in the polymerization. US '040 does not teach an adhesive comprising ammonium persulfate as urged by the examiner.

US '040 fails to disclose an adhesive comprising applicant's required polymer and fails to disclose an adhesive comprising a therapeutic agent as required in the practice of applicants' invention. The polymer of US '040 does not contain each of the required limitations of applicants' claimed invention and, as such, fails to anticipate claims 1, 3-7 and 9.

Claims 1, 3-7 and 9 are not anticipated by US '040. Reconsideration and withdrawal of this Section 102 rejection is requested.

Claims 1-6, 9-14 and 22 are rejected under 35 U.S.C. § 102(b) as being anticipated by EP 0 531 938.

The examiner (office action, numbered paragraph 4, bottom of page 4) interprets applicants' claims as requiring polymer prepared from monomers selected from the group consisting of alkyl acrylate monomer, alkyl methacrylate monomer and polymerizable non-cyclic nitrogen-containing monomer, and as further requiring 50-98% alkyl acrylate monomers and/or alkyl methacrylate monomers. The examiner acknowledges that the claims also require a therapeutic agent.

EP '938 is cited by the examiner as disclosing medical preparations for percutaneous absorption of drugs (the examiner refers to the abstract) The preparation is applied on a substrate, i.e., a backing (the examiner refers to page 3, lines 14-20). The preparation comprises a pressure sensitive acrylic based layer obtained by polymerizing 60-98 % by weight of alkyl(meth)acrylate monomer having 4-15 carbon atoms in the alkyl moiety and from 2-40 % by weight of monomer copolymerizable with alkyl (meth)acrylate (the examiner refers to page 4, lines 13-19). The alky(meth)acrylate is ethylhexyl acrylate (the examiner refers to page 4, lines 21-22 and example 1) . The monomer copolymerizable with the alkyl(meth) acrylate includes methacrylamide, which the examiner urges meets claim 6 and (meth)acrylonitrile, which the examiner urges meets claim 3. The drugs included in the adhesive layer include analgesics, hypnotics and sedatives (the examiner refers to page 6, lines 15-21). The examiner urges that the Tg as claimed by claim 4 is inherent for the specific polymer.

Applicants' claim 1 is directed to an adhesive composition comprising an acrylic polymer and a therapeutic agent. The acrylic polymer is made from monomers selected from the group consisting of alkyl acrylate monomer, alkyl methacrylate monomer and polymerizable non-cyclic

nitrogen-containing monomers. The alkyl acrylate monomer and alkyl methacrylate monomers used to prepare the polymer are further characterized as having up to about 18 carbon atoms in the alkyl group. The polymerizable non-cyclic nitrogen-containing monomers are further characterized as being selected from the group consisting of N-substituted acrylamide monomers, N-substituted methacrylamide monomers, vinylacetamides, nitriles, and mixtures thereof. The acrylic polymer required for use comprises, on a dry weight basis of the total monomer weight of the polymer, from about 50 to about 98% of the alkyl acrylate monomers and/or alkyl methacrylate monomers and from about 2 to about 50% of the polymerizable non-cyclic nitrogen-containing monomers, lacks functional groups containing reactive hydrogen moieties and contains no post-polymerization chemical crosslinker.

Applicants disagree that the claimed invention is anticipated by EP'938.

The examiner mischaracterizes the teaching of EP'938 by picking and choosing isolated passages of EP'938 while ignoring other relevant passages and the EP'938 disclosure as a whole. As noted above, applicants' acrylic polymer lacks functional groups containing reactive hydrogen moieties and contains no post polymerization chemical crosslinker. In contrast, EP'938 discloses a crosslinked pressure sensitive adhesive gel material. The examiner is referred to the monomers recited on page 4, lines 24 et seq. and to the disclosure at page 4, lines 46-50:

> Of such various acrylic ester-based polymers, copolymers obtained by copolymerizing an alkyl (meth)acrylate and at least one of the above-described carboxyl group-containing monomers and hydroxyl group-containing monomers, as essential components, and if required one or more of the other monomers described above are advantageously used in the present invention from the standpoint of control of the amount of crosslinking sites or control of tackiness properties.

The examiner is referred to the examples, which use acrylic acid (examples 1-6) and 2-hydroxyethyl acrylate (7 and 8) and which are are crosslinked.

EP'938 fails to teach a pressure sensitive adhesive comprising an acrylic polymer that lacks functional groups containing reactive hydrogen moieties and contains no post polymerization chemical crosslinker. EP'938 fails to disclose an adhesive comprising applicant's required polymer and fails to disclose such an adhesive that also comprises a therapeutic agent as required in the practice of applicants' invention. The polymer of EP'938 does not contain each of the required limitations of applicants' claimed invention and, as such, fails to anticipate claims 1, 3-6, 9-14 and 22.

Claims 1, 3-6, 9-14 and 22 are not anticipated by EP'938. Reconsideration and withdrawal of this Section 102 rejection is requested.

Claim 7 is rejected under 35 U.S.C. § 103 (a) as being obvious over EP 0 531 938 in view of US 3,494,070.

The examiner urges that while EP '938 teaches use of methacrylamide, the use of octyl acrylamide is not explicitly taught. It is, however, the position of the examiner that it would have been obvious to the skilled artisan to replace the acrylamide monomer of EP '938 with octyl acrylamide disclosed in US '070.

Applicants disagree. The claimed invention would not have been obvious from the combined disclosures of EP '938 and US '070. Use of octyl acrylamide in the practice of the EP '938 invention would not have resulted in an adhesive comprising a acrylic polymer that lacks functional groups containing reactive hydrogen moieties and contains no post polymerization chemical crosslinker.

Claim 7 is not obvious over EP'938 in view of US '070. Reconsideration and withdrawal of this Section 103 rejection is requested.

Claims 15-17 are rejected under 35 U.S.C. § 103 (a) as being obvious over EP 0 531 938 in view of 6,139,866.

The examiner urges that while EP '938 teaches delivery use of analgesics, sedatives and hypnotic drugs, the use of fentanyl is not explicitly taught. It is, however, the position of the examiner that it would have been obvious to the skilled artisan to replace the analgesic, sedative or hypnotic drugs of EP '938 with fentanyl that is taught in US '866 as being suitable for transdermal administration.

Applicants disagree. The claimed invention would not have been obvious from the combined disclosures of EP '938 and US '866 .Use of fentanyl in the practice of the EP '938 invention would not have resulted in an adhesive comprising a acrylic polymer that lacks functional groups containing reactive hydrogen moieties and contains no post polymerization chemical crosslinker.

Claims 15-17 are not obvious over EP'938 in view of US '866. Reconsideration and withdrawal of this Section 103 rejection is requested.

Claims 18 and 20 are rejected under 35 U.S.C. § 103 (a) as being obvious over EP 0 531 938 in view of US 5,458,885.

The examiner urges that while EP '938 teaches use of two or more alkyl (meth)acrylates in the polymer, the use of 2-ethylehexyl acrylate and methyl acrylate as required by claims 18 and 20 is not explicitly taught. It is, however, the position of the examiner that it would have

been obvious to the skilled artisan to replace the acrylate monomer of EP'935 with methyl acrylate and 2-ethylehexyl acrylate disclosed in is taught in US '885.

Applicants disagree. The claimed invention would not have been obvious from the combined disclosures of EP '938 and US '885. There is no suggestion to use only those monomers that would result in an acrylate polymer that lacks functional groups containing reactive hydrogen moieties and contains no post polymerization chemical crosslinker and such an adhesive would be contrary to the teachings of EP '938.

Claims 18 and 20 are not obvious over EP'938 in view of US '885. Reconsideration and withdrawal of this Section 103 rejection is requested.

Claims 19 and 21 are rejected under 35 U.S.C. § 103 (a) as being obvious over EP 0 531 938 in view of US 5,458,885 and further in view of US 3,494,070.

The examiner urges that while the combined teaching of EP '938 and US '885 teach use of 2-ethylehexyl acrylate and methyl acrylate, the use of octyl-acrylamide as required by claims 19 and 21 is not explicitly taught. It is, however, the position of the examiner that it would have been obvious to the skilled artisan to use the octyl-acrylamide of US '040 with methyl acrylate and 2-ethylehexyl acrylate disclosed in the combined teachings of EP '938 and US '885.

Applicants disagree. The claimed invention would not have been obvious from the combined disclosures of EP '938 and US '885, further in view of US '040. There is no suggestion to use only those monomers that would result in an acrylate polymer that lacks functional groups containing reactive hydrogen moieties and contains no post polymerization chemical crosslinker and such an adhesive would be contrary to the teachings of EP '938.

Claims 19 and 21 are not obvious over EP'938 in view of US '885 and further in view of US '040. Reconsideration and withdrawal of this Section 103 rejection is requested.

Applicants submit that claims 1, 3-7 and 9-22 are in condition to be allowed. Early and favorable action is requested.

Respectfully submitted,

/Cynthia L. Foulke/

March 20, 2008

Cynthia L. Foulke
Reg. No. 32,364

National Starch and Chemical Company
10 Finderne Avenue
Bridgewater, New Jersey 08807-0500
Telephone No.: 908-685-7483